On January 21, 2020, the U.S. Food and Drug Administration (FDA) approved TEPEZZA™ (teprotumumab-trbw) for the treatment of thyroid eye disease (TED) in adults. Medical College of Wisconsin researchers in the Department of Ophthalmology & Visual Sciences participated in both clinical trials leading to this highly anticipated drug's approval.

Thyroid eye disease is a rare, debilitating auto-immune disease associated with the outward bulging of the eye that can cause symptoms including vision loss, eye pain, double vision, light sensitivity or difficulty closing the eye. Although this condition impacts a small number of individuals, thyroid eye disease can be incapacitating; symptoms can lead to the progressive inability to perform important daily activities, such as driving or working. According to the FDA, TEPEZZA™ is the first drug approved for the treatment of TED. Clinicians in ophthalmology and endocrinology are working hard to ensure TEPEZZA™ is available for Froedtert & MCW patients soon.

Results of the most recent Phase III clinical trial evaluating teprotumumab (the "OPTIC" trial) were recently published in the New England Journal of Medicine, in an article co-authored by local principal investigator and Orbital and Oculoplastic Surgery Section Chief Dr. Gerald J. Harris. Sub-investigators Dr. Sang Hong and Dr. Timothy Wells also enrolled participants in the OPTIC trial, with support from study coordinators Ellie Dorsey Veh and Katie McKenney. The research team partnered with the CTSI's Adult and Pediatric Translational Research Units to conduct this trial, which required participants to receive IV infusions every three weeks for six months.

The Medical College of Wisconsin was one of only seven institutions in the United States to participate in the OPTIC study, with a total of 13 sites participating in the study worldwide.

The FDA granted the approval of TEPEZZA™ to Horizon Therapeutics Ireland DAC.

Read the full study in the New England Journal of Medicine.

Read the press release from the FDA.